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Stent

Stent

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Description

[0001] This invention is in the field of stents for maintaining patency of any one of a multiplicity of vessels of the human body.

[0002] In the last decade, many different designs of stents have been used to maintain patency of arteries and other vessels of the human body. In all such devices, hoop strength is an important characteristic. Specifically, the stent must have enough hoop strength to resist the elastic recoil exerted by the vessel into which the stent is placed. The Mass stent described in the U. S. Patent No. 4,553,545 and the Dotter stent described in U.S. Patent No. 4,503, 569 are each open helical coils. The Palmaz stent described in the U.S. Patent No. 4,733,665 is of the "chinese finger" design. The Gianturco-Rubin stent currently sold by Cook, Inc. is another stent design which like the stents of Mass, Dotter and Palmaz does not have any closed circular member to optimize hoop strength. EP-A-566 807 is used as the basis for the preamble of claim 1.

[0003] The ideal arterial stent utilizes a minimum wire size of the stent elements to minimize thrombosis at the stent site after implantation. The ideal arterial stent also posses sufficient hoop strength to resist elastic recoil of the artery. Although the optimum design for maximizing hoop strength is a closed circular structure, no prior art stent has been described which has a small diameter when percutaneously inserted into a vessel and which expands into the form of multiplicity of closed circular structures (i.e. rings) when expanded outward against the vessel wall.

[0004] In accordance with the invention, there is provided a stent structure for maintaining patency of a vessel of a human body, the stent structure having a longitudinal axis and comprising first structures forming longitudinals the first structures being joined by second structures around the longitudinal axis, characterised in that at least two longitudinals have an undulating shape so as to enhance longitudinal flexibility.

[0005] An embodiment of the invention is described hereinafter, by way of example only with reference to the accompanying drawings, in which:

FIG. 1 is a side view of the stent after it has been deployed; i.e., in its post-deployment form;

FIG. 2 is a transverse cross section at section 2-2 of FIG. 1 illustrating how the longitudinals are joined to the rings;

FIG. 3 is a cross section at section 3-3 of FIG. 2 showing the joining of a single ring to the longitudinals;

FIG. 4 is a side view of the stent prior to being mounted onto a stent delivery catheter; i.e., in the form of an initial structure;

FIG. 5 is a transverse cross section at section 5-5 of FIG. 4 illustrating how the longitudinals are joined to the ovals;

FIG. 6 is a side view of a pre-deployment form of the stent structure in which the ovals have been folded into a small diameter cylinder that is placed around a deflated balloon situated near the distal end of a stent delivery catheter;

FIG. 7 is a partial side view of a pre-deployment stent structure showing only two of a multiplicity of folded ovals formed around an expandable balloon in which the ovals are folded in an alternative manner as compared with FIG. 6;

FIG. 8 is a side view of a post-deployment stent structure according to the present invention which utilizes two undulating longitudinals on opposite sides of the stent for improved placement in curved vessels; and

FIG. 9 is a side view of a stent as etched out of a small diameter metal cylinder as a single piece of metal.

[0006] FIG. 1 is a side view of an embodiment of a cylindrical stent 1 shown in its post-deployment configuration. The stent 1 has a multiplicity of rings 2 which are spaced apart by four wires called longitudinals. As seen in FIGS. 1 and 2, at the top of the stent is longitudinal 4T, at the bottom is longitudinal 4B, at the left side is longitudinal 4L and at the right side is longitudinal 4R. Although FIGS. 1 and 2 show 7 rings and 4 longitudinals, it is apparent that the stent can be made longer by adding rings or increasing the separation between rings. In a similar manner, the stent can be made shorter by reducing the number of rings or decreasing the spacing between rings. Also variable spacing of the rings is envisioned for accomplishing a variety of purposes including increased hoop strength at a particular section of the stent. Also, it is envisioned that the two or more longitudinals could be utilized for this stent design with a maximum number being 32.

[0007] FIGS. 2 and 3 illustrate the joining of the longitudinals to the rings. Specifically the longitudinals can be placed into cutouts in the form of notches 5 located on the outside perimeter of the ring 2. The longitudinals can then be spot welded, adhesively bonded or joined by any variety of means to the rings 2. It is also envisioned that the longitudinals could be placed on the inside perimeter of the ring 2, or holes could be mechanically or laser drilled through the ring 2 for placement therethrough of the longitudinals.

[0008] FIGS. 4 and 5 illustrate a stent 1' shown in one particular form in which it could be fabricated; i.e., in an initial structure form. Specifically, FIGS. 4 and 5 show that this initial form of the stent 1' is a multiplicity of par-

allel ellipses or ovals 2' each oval having the same minor axis dimension m and major axis dimension M. The oval's minor axis passes through the center of the longitudinals 4L and 4R. The oval's major axis passes through the center of the longitudinals 4T and 4B. It is important to note that, if it is desired to have a final outside diameter D (as seen in FIG. 2) of the ring 2 after it is fully deployed, then it can be shown that D is given by the equation $D^2 = 1/2\ (m^2 + M^2)$.

[0009] To place the stent design of FIGS. 4 and 5 onto a balloon that is mounted near the distal end of a stent delivery catheter, it is necessary to fold the ovals 2' around that balloon. Specifically, the pre-deployment cylindrical stent 1" can be formed onto an expandable balloon 6 as shown in FIG. 6 by folding the ovals 2' about the dotted line F (which is the minor axis of the oval 2') as shown in FIG. 5. Specifically, as seen in FIG. 4, the top and bottom of the ovals 2' could be held stationery while the side longitudinals 4R and 4L are pushed to the left which results in the pre-deployment structure which is shown as the stent 1" in FIG. 6. An optimum design has the folded ovals 2" as shown in FIG. 6 with the stent 1" being a cylinder whose outside diameter is equal in size to the minor axis dimension m. When the balloon 6 of FIG. 6 is expanded, the pre-deployment stent 1" structure forms the post-deployment stent 1 structure having circular rings 2 as shown in FIGS. 1 and 2.

[0010] The stent 1'" is an alternative embodiment for a pre-deployment structure of the stent as it is placed onto a balloon. Specifically, FIG. 7 shows 2 folded rings 2'" of a multiple ring stent 1'". The stent 1'" being formed by holding the top and bottom of the stent 1' of FIG. 4 stationery while pushing the longitudinal 4R to the left and pushing the longitudinal 4L to the right. Like the stent 1" of FIG. 6, when mounted onto a balloon, the stent 1'" has a cylindrical shape with a diameter equal to the dimension m.

[0011] FIGS. 1 to 7 inclusive illustrate stents that employ longitudinals that are formed from generally straight wires. FIG. 8 shows an embodiment of a stent 10 according to the present invention that has two undulating longitudinals. Specifically, the left side longitudinal 14L (shown as dotted lines) and the right side longitudinal 14R are each undulating shaped longitudinals. A stent such as stent 10 could have two or more undulating longitudinals. Such a stent would bend more easily during insertion into a vessel and would be more readily adaptable for placement in curved vessels such as some coronary arteries.

[0012] Typically, the rings and longitudinals of the stents would be made of the same material. Typical metals used for such a stent would be stainless steel, tantulum, titanium, or a shape memory metal such as Nitinol. If Nitinol is used, the stent would be heat treated into the shape at body temperature having circular rings 2 as shown in FIGS. 1 and 2. The rings could then be distorted into ovals as shown in FIGS. 4 and 5 and then mounted onto a stent delivery catheter which does not employ a balloon but is of the more general shape described in the previously cited U.S. Patent No. 4,553,545 by C.T. Dotter. Such a design would provide the desired stent structure having a multiplicity of generally circular rings instead of the Dotter design of a helical spring which inherently has a lesser hoop strength.

[0013] It should be understood that once the ovals are folded onto a stent delivery catheter, when they fully deploy, they do not form perfectly circular rings as shown in FIG. 2, but rather they are of a generally circular shape. Such comparatively small deviations from an exactly circular shape do not appreciably decrease hoop strength because they are in fact closed structures that are almost exactly circular.

[0014] It should also be understood that at least part of the end rings of the stent could be fabricated from or coated with a radiopaque metal such as tantalum or gold to provide a fluoroscopic indication of the stent position within a vessel. However, the other rings and the longitudinals could be made from a much less dense metal which would provide less obscuration of the central region within the stent. For example, the stent rings and longitudinals could all be fabricated from titanium or a titanium alloy except the end rings which could be formed from gold which is then plated with titanium. Thus, the entire outside surface of the stent would be titanium, which is known to be a comparatively nonthrombogenic metal while the gold in the end rings provides an improved fluoroscopic image of the stent extremities.

[0015] The dimensions of stent rings are typically 0.1 to 0.3 mm thick, with a width of 0.1 to 0.5 mm and an outside diameter D between 2.0 and 30.0 mm depending on the luminal diameter of the vessel into which it is inserted. The length of the stent could be between 1 and 10 cm. The wire diameter for the longitudinals would typically be between 0.05 and 0.5 mm.

[0016] Although the designs described above illustrate separate longitudinals attached to a multiplicity of rings, this invention also contemplates an initial stent structure which is chemically etched from thin-walled tubing having an oval transverse cross section. Thus the oval and longitudinals would be formed from a single piece of metal thus precluding the need for attaching the longitudinals to the rings. In a similar manner laser or EDM machining could be used to form the stent from a thin-walled tube.

[0017] It is further anticipated that a pre-deployment stent structure 20 as shown in FIG. 9 could be formed from a thin-walled cylindrical tube whose inside diameter is slightly smaller than the outside diameter of the balloon 6 shown in FIG. 6. A pattern such as that shown in either FIG. 6 or FIG. 7 could be photoetched onto a thin-wallcd metal cylinder. The one piece structure 20 shown in FIG. 9 has folded ovals 22 and longitudinals 23T, 24B, 24R and (not shown) 24L. This pre-deployment stent structure 20 could then be mounted onto the expandable balloon; the stent having sufficient elastic

recoil to firmly grasp down onto the balloon.

[0018] Accordingly, there has been described herein a stent structure for maintaining patency of a vessel of a human body, the stent structure having a multiplicity of structures forming longitudinals having an undulating shape so as to enhance longitudinal stability.

[0019] Various other modifications, adaptations, and alternative designs are of course possible in light of the above teachings and within the scope of the invention as disclosed in the appended claims.

Claims

1. A stent structure (10) for maintaining patency of a vessel of a human body, the stent structure (10) having a longitudinal axis and comprising first structures forming longitudinals (14L, 14R), the first structures being joined by second structures around the longitudinal axis, characterised in that at least two longitudinals have an undulating shape so as to enhance longitudinal flexibility.

2. A stent structure (10) according to Claim 1, wherein said second structures comprise at least a pair of longitudinally displaced elements (12), said longitudinals (14) being secured to at least two of said elements.

3. A stent structure (10) according to Claim 2, wherein said elements (12) are formed in a closed contour.

4. A stent structure (10) according to Claim 2, wherein said second structures comprise a pair of opposing end elements (12) having a radiopacity value different than a radiopacity value of other elements (12) forming said second structures.

5. A stent structure (10) according to any one of Claims 2 to 4, wherein said elements (12) comprise a metal composition.

6. A stent structure (10) according to any one of Claims 2 to 5, wherein said elements (12) comprise wire members.

7. A stent structure (10) according to any preceding claim, wherein said longitudinals comprise a metal composition.

8. A stent structure (10) according to any preceding claim, wherein said longitudinals (14) comprise wire members.

9. A stent structure (10) according to any preceding claim, wherein said stent structure (10) is formed from a metal having a shape memory characteristic.

10. A stent structure (10) according to any one of Claims 1 to 4, wherein the stent structure (10) is formed as a one piece structure that is photo-etched from a single piece of metal.

11. A stent structure (10) according to any one of Claims 1 to 4, wherein the stent structure (10) is formed as a one piece structure that is EDM machined from a thin-walled tube.

12. A stent structure (10) according to any one of Claims 1 to 4, wherein the stent structure (10) is formed as a one piece structure that is laser machined from a thin-walled tube.

13. A stent structure (10) according to any preceding claim, wherein at least two of said longitudinal structures (14L, 14R) have at least one straight section and at least one undulating section with each said straight section being joined continuously to said at least one undulating section, the straight sections of all of the longitudinal structures (14L, 14R) being generally parallel to the longitudinal axis of the stent (10), the undulating section of each longitudinal structure (14L, 14R) being of a generally curved shape so as to allow each undulating longitudinal structure to readily change length during insertion of the stent structure into a curved vessel of a human body.

14. A stent structure (10) according to Claim 13, wherein the undulating section of the longitudinal structures (14L, 14R) extends first in one circumferential direction and then extend in the opposite circumferential direction.

15. A stent structure (10) according to Claim 13 or Claim 14, wherein each undulating section is joined at each of its ends to a straight section.

16. A stent structure (10) according to any one of Claims 13 to 15, wherein at least two of said longitudinal structures each comprise a series of undulating sections.

Patentansprüche

1. Stentstruktur (10) zur Aufrechterhaltung der Durchgängigkeit eines Gefäßes eines menschlichen Körpers, wobei die Stentstruktur (10) eine Längsachse hat und erste Strukturen aufweist, welche Längselemente (14L, 14R) bilden, wobei die ersten Strukturen durch zweite Strukturen um die Längsachse verbunden sind, dadurch gekennzeichnet, daß mindestens zwei Längselemente eine Wellenform besitzen, um die Längsflexibilität zu verbessern.

2. Stentstruktur (10) nach Anspruch 1, wobei die zweiten Strukturen mindestens ein Paar von längs versetzten Elementen (12) aufweisen, wobei die Längselemente (14) an mindestens zwei der Elemente befestigt sind.

3. Stentstruktur (10) nach Anspruch 2, wobei die Elemente (10) in einer geschlossenen Kontur geformt sind.

4. Stentstruktur (10) nach Anspruch 2, wobei die zweiten Strukturen ein Paar von gegenüberliegenden Endelementen (12) aufweisen, die einen Strahlenundurchlässigkeitswert haben, der sich von dem anderer Elemente (12), welche die zweiten Strukturen bilden, unterscheidet.

5. Stentstruktur (10) nach einem der Ansprüche 2 bis 4, wobei die Elemente (12) eine Metallzusammensetzung aufweisen.

6. Stentstruktur (10) nach einem der Ansprüche 2 bis 5, wobei die Elemente (12) Drahtteile aufweisen.

7. Stentstruktur (10) nach einem vorhergehenden Anspruch, wobei die Längselemente eine Metallzusammensetzung aufweisen.

8. Stentstruktur (10) nach einem vorhergehenden Anspruch, wobei die Längselemente (14) Drahtteile aufweisen.

9. Stentstruktur (10) nach einem vorhergehenden Anspruch, wobei die Stentstruktur (10) aus einem Metall gebildet ist, welches ein Formerinnerungsvermögen hat.

10. Stentstruktur (10) nach einem der Ansprüche 1 bis 4, wobei die Stentstruktur (10) als eine Struktur aus einem Stück gebildet ist, die aus einem einzigen Metallstück durch Photoätzen gebildet ist.

11. Stentstruktur (10) nach einem der Ansprüche 1 bis 4, wobei die Stentstruktur (10) aus einer Struktur in einem Stück gebildet ist, die aus einem dünnwandigen Rohr durch Funkenerosion bearbeitet (EDM machining) ist.

12. Stentstruktur (10) nach einem der Ansprüche 1 bis 4, wobei die Stentstruktur (10) aus einer Struktur in einem Stück gebildet ist, wie aus einem dünnwandigen Rohr durch Laserbearbeitung erstellt ist.

13. Stentstruktur (10) nach einem vorhergehenden Anspruch, wobei mindestens zwei der Längsstrukturen (14L, 14R) mindestens einen geraden Abschnitt und mindestens einen Abschnitt mit Wellenform haben, wobei jeder gerade Abschnitt kontinuierlich mit dem mindestens einen Wellenformabschnitt verbunden ist, die geraden Abschnitte aller der Längsstrukturen (14L, 14R) im allgemeinen parallel zu der Längsachse des Stent (10) liegen, der wellenförmige Abschnitt jeder Längsstruktur (14L, 14R) im allgemeinen gekrümmte Form hat, um jeder wellenförmigen Längsstruktur die Möglichkeit zu geben, leicht die Länge während des Einführens der Stentstruktur in ein gekrümmtes Gefäß eines menschlichen Körpers zu verändern.

14. Stentstruktur (10) nach Anspruch 13, wobei der wellenförmige Abschnitt der Längsstrukturen (14L, 14R) sich erst in eine Umfangsrichtung erstreckt und sich dann in die entgegengesetzte Umfangsrichtung erstreckt.

15. Stentstruktur (10) nach Anspruch 13 oder Anspruch 14, wobei jeder wellenförmige Abschnitt an jedem seiner Enden mit einem geraden Abschnitt verbunden ist.

16. Stentstruktur (10) nach einem der Ansprüche 13 bis 15, wobei mindestens zwei der Längsstrukturen jeweils eine Reihe von wellenförmigen Abschnitten aufweisen.

Revendications

1. Structure de stent (10) pour maintenir l'état non obstrué d'un vaisseau d'un corps humain, la structure de stent (10) ayant un axe longitudinal et comprenant des premières structures formant des éléments longitudinaux (14L, 14R), les premières structures étant jointes par des secondes structures autour de l'axe longitudinal, caractérisée en ce qu'au moins deux éléments longitudinaux ont une forme ondulée de façon à améliorer la flexibilité longitudinale.

2. Structure de stent (10) selon la revendication 1, dans laquelle lesdites secondes structures comprennent au moins un couple d'éléments déplacés de façon longitudinale (12), lesdits éléments longitudinaux (14) étant fixés à au moins deux desdits éléments.

3. Structure de stent (10) selon la revendication 2, dans laquelle lesdits éléments (12) sont formés avec un contour fermé.

4. Structure de stent (10) selon la revendication 2, dans laquelle lesdites secondes structures comprennent un couple d'éléments d'extrémité opposés (12) ayant une valeur de radio-opacité différente d'une valeur de radio-opacité d'autres éléments (12) formant lesdites secondes structures.

5. Structure de stent (10) selon l'une quelconque des revendications 2 à 4, dans laquelle lesdits éléments (12) sont constitués par une composition métallique.

6. Structure de stent (10) selon l'une quelconque des revendications 2 à 5, dans laquelle lesdits éléments (12) sont constitués par des éléments en fil métallique.

7. Structure de stent (10) selon l'une quelconque des revendications précédentes, dans laquelle lesdits éléments longitudinaux sont constitués par une composition métallique.

8. Structure de stent (10) selon l'une quelconque des revendications précédentes, dans laquelle lesdits éléments longitudinaux (14) sont constitués par des éléments en fil métallique.

9. Structure de stent (10) selon l'une quelconque des revendications précédentes, dans laquelle ladite structure de stent (10) est formée à partir d'un métal ayant une caractéristique de mémoire de forme.

10. Structure de stent (10) selon l'une quelconque des revendications 1 à 4, dans laquelle la structure de stent (10) est formée en tant que structure d'un seul tenant qui est photogravée à partir d'une seule pièce de métal.

11. Structure de stent (10) selon l'une quelconque des revendications 1 à 4, dans laquelle la structure de stent (10) est formée en tant que structure d'un seul tenant qui est usinée par étincelage (EDM) à partir d'un tube à paroi mince.

12. Structure de stent (10) selon l'une quelconque des revendications 1 à 4, dans laquelle la structure de stent (10) est formée en tant que structure d'un seul tenant qui est usinée par laser à partir d'un tube à paroi mince.

13. Structure de stent (10) selon l'une quelconque des revendications précédentes, dans laquelle au moins deux desdites structures longitudinales (14L, 14R) ont au moins une partie droite et au moins une partie ondulée, chaque dite partie droite étant jointe de façon continue à ladite au moins une partie ondulée, les parties droites de toutes les structures longitudinales (14L, 14R) étant globalement parallèles à l'axe longitudinal du stent (10), la partie ondulée de chaque structure longitudinale (14L, 14R) étant d'une forme globalement incurvée de façon à permettre à chaque structure longitudinale ondulée de changer aisément de longueur pendant l'insertion de la structure de stent dans un vaisseau incurvé d'un corps humain.

14. Structure de stent (10) selon la revendication 13, dans laquelle la partie ondulée des structures longitudinales (14L, 14R) s'étend d'abord dans une direction circonférentielle particulière et s'étend ensuite dans la direction circonférentielle opposée.

15. Structure de stent (10) selon la revendication 13 ou la revendication 14, dans laquelle chaque partie ondulée est jointe au niveau de chacune de ses extrémités à une partie droite.

16. Structure de stent (10) selon l'une quelconque des revendications 13 à 15, dans laquelle au moins deux desdites structures longitudinales comprennent chacune une série de parties ondulées.

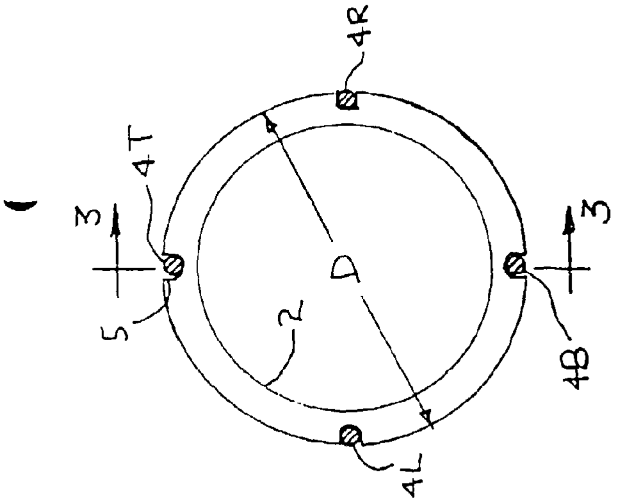

FIG. 2

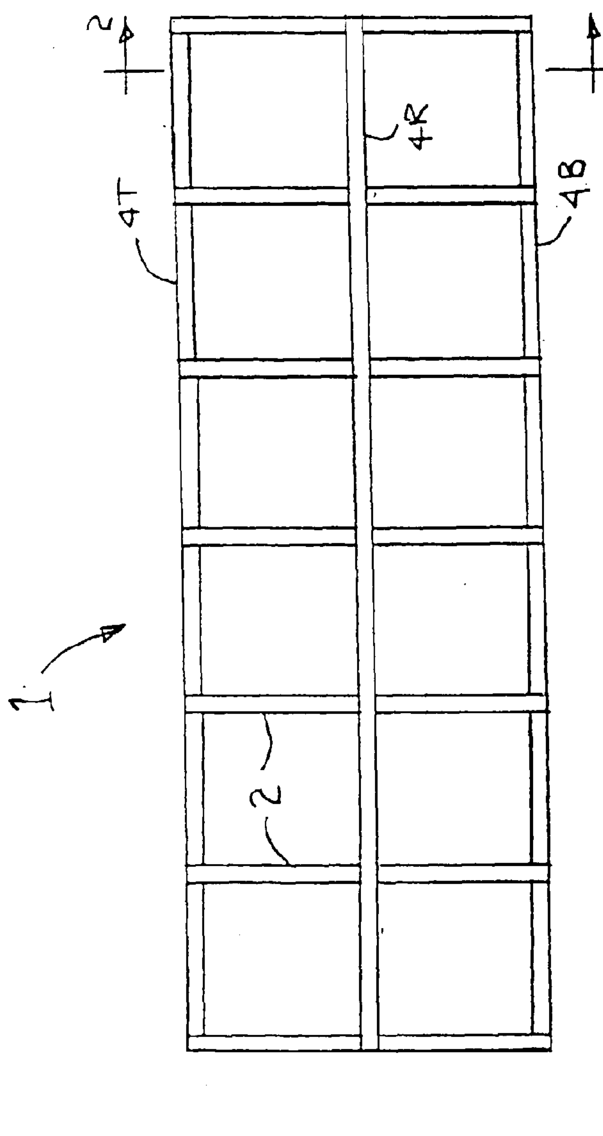

FIG. 1

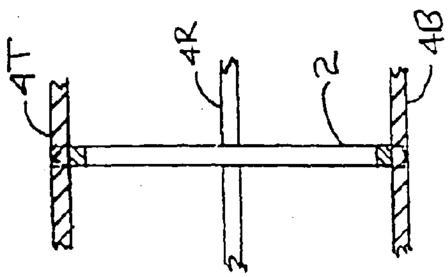

FIG. 3

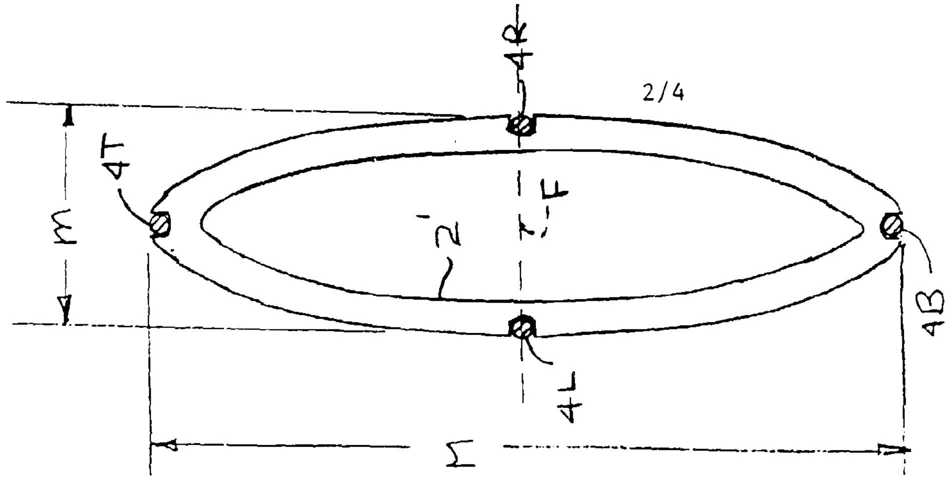

FIG. 5

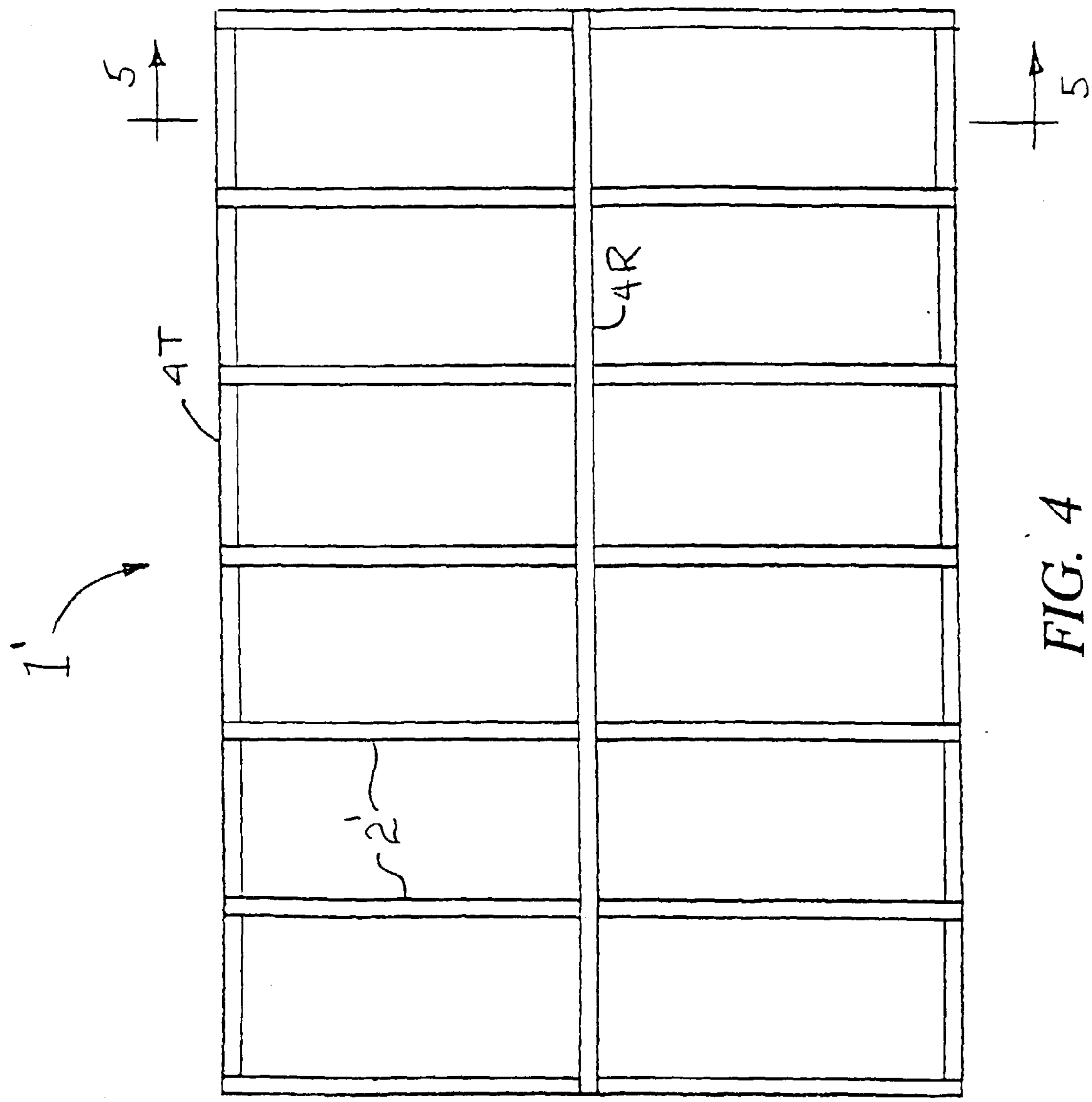

FIG. 4

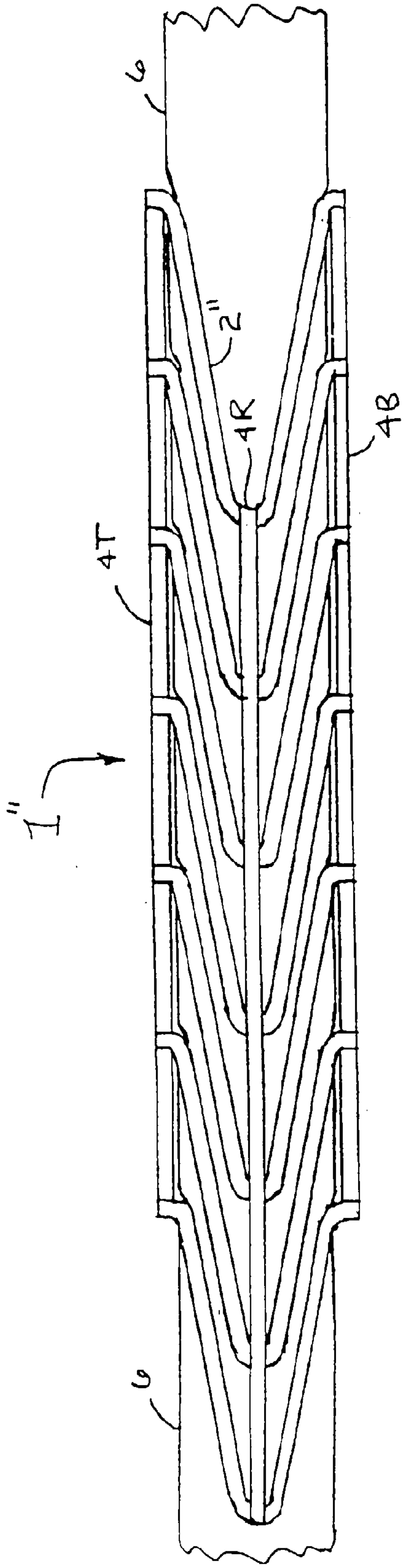

FIG. 6

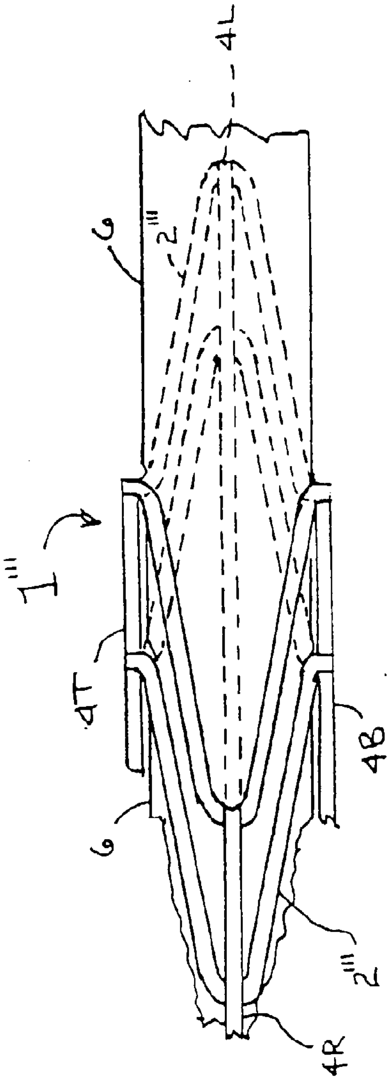

FIG. 7

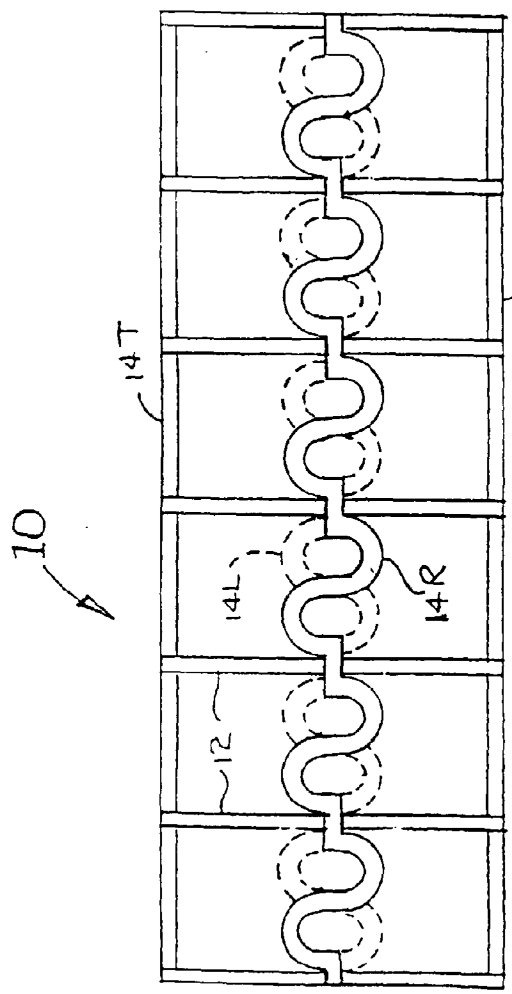

FIG. 8

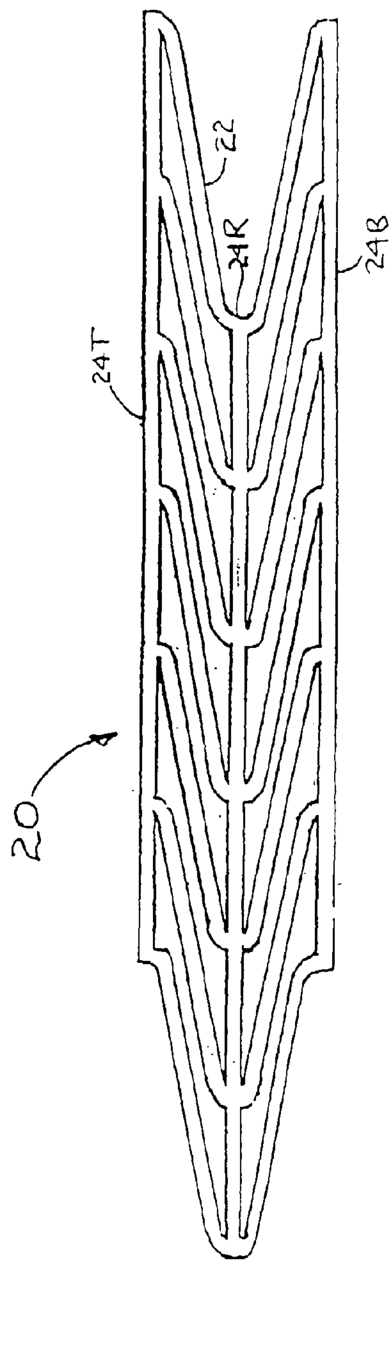

FIG. 9